

REMARKS

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

This amendment adds, changes and/or deletes claims in this application. A detailed listing of all claims that are, or were, in the application, irrespective of whether the claim(s) remain under examination in the application, is presented, with an appropriate defined status identifier.

Claim 11 is requested to be cancelled.

Claims 23-25 are requested to be added. New claim 23 substantially incorporates subject matter from cancelled claim 11 and includes the limitation “the neutral core...*consists of a substance selected from the group consisting of sugar, starch, mannitol, sorbitol, xylitol, cellulose, talc, and mixtures thereof.*” Support for new claim 23 may be found at paragraph [0022]. Support for new claims 24 and 25, which depend from new claim 23, may be found at paragraphs [0022] and [0023].

Claims 12, 13, and 15-20 are requested to be amended to recite dependency from new claim 23.

After amending the claims as set forth above, claims 12-20 and 23-25 are now pending in this application.

Claim Rejections - 35 U.S.C. § 102

In the Office Action, dated September 8, 2004, and in the Advisory Action dated December 13, 2004, the Examiner maintained the rejection of Claims 11-13 and 15-17 under 35 U.S.C. § 102(b) as being anticipated by Franz *et al.* (U.S. 4,411,882). The Examiner asserts that “‘neutral core’ should be given its broadest reasonable interpretation consistent with the specification.” As such, the Examiner argues that “neutral” should be interpreted to mean “free of charge” and that “core” should be interpreted to mean the innermost layer.

Finding as such, the Examiner contends that Franz *et al.* meets all the elements of the instant claims.

Applicants have amended the claims to facilitate prosecution and respectfully request that the Examiner reconsider the rejection in view new claim 23, which is patterned after cancelled claim 11. New claim 23 includes the limitation “the neutral core has a particle size of between 200 and 1600 μm and *consists of a substance selected from the group consisting of sugar, starch, mannitol, sorbitol, xylitol, cellulose, talc, and mixtures thereof.*” In contrast, Franz *et al.* emphasizes that the “core” includes substances other than “sugar, starch, mannitol, sorbitol, xylitol, cellulose, talc, and mixtures thereof.” Franz *et al.* states “[t]he term ‘core’ comprises any mixture of an ergot alkaloid and a sterol ether, if desired in admixture with further physiologically acceptable material, that can be surrounded by an enteric-coating.” (See Franz *et al.*, col. 1 lines 45-48.) Franz *et al.* does not teach or suggest a core that “consists of a substance selected from the group consisting of sugar, starch, mannitol, sorbitol, xylitol, cellulose, talc, and mixtures thereof.” As such, Applicants respectfully contend that Franz *et al.* does not anticipate the claims as amended.

Although Applicants have amended the claims to facilitate prosecution of the application, Applicants maintain that the Examiner has not given the term “neutral” its broadest reasonable interpretation consistent with the specification. The Examiner maintains that the broadest reasonable interpretation of “neutral” consistent with the specification is “free of charge.” Applicants disagree and maintain that the Examiner’s interpretation of “neutral” is unreasonable and inconsistent with the subject matter of the specification.

Applicants maintain that the limitation “neutral” is more reasonably interpreted to be synonymous with “inert.” See dictionary.com definitions of “neutral” and “inert,” copy of webpages enclosed herewith and available at <http://dictionary.reference.com/search?q=neutral> (hereinafter “neutral definition”) and <http://dictionary.reference.com/search?q=inert> (hereinafter “inert definition”), respectively. On page six (6) of the “neutral definition” from Webster’s Revised Unabridged Dictionary © 1996, 1998 MICRA, Inc., “neutral” is defined as “3: having only a limited ability to react chemically, **not active; ‘inert matter’**; ‘an indifferent

chemical in a reaction' [*syn: inert*, indifferent].'" See "neutral definition" at page 6 of 7 (emphasis added).

Similarly, on page three (3) of the "inert definition" from Webster's Revised Unabridged Dictionary © 1996, 1998 *MICRA, Inc.*, "inert" is defined as "having only a limited ability to react chemically; *not active*; 'inert matter'; 'an indifferent chemical in a reaction' [*syn: indifferent, neutral*]." See "inert definition" at page 3 of 4 (emphasis added). As such, "neutral" is reasonably interpreted to mean "inert," especially in a chemical context. Applicants note that the instant application relates to *pharmaceutical preparations* and contend that Applicants' proposed interpretation of "neutral" (*i.e.*, "inert") is *more reasonable* and *more consistent with the specification* than the Examiner's proposed interpretation (*i.e.*, "free of charge").

Further, those skilled in the art have interpreted "neutral" to mean "inert." Applicants have enclosed herewith product information sheets for NPpharm Suglets® (hereinafter "NPpharm Suglets®") and IPSsrl Pharmaceutical Sugar Spheres (hereinafter "IPSSrl Sugar Spheres"). As indicated by NPpharm, Suglets® are "Sphere de Sucre – *Neutral Pellets* – Sugar Spheres – *Neutral Core*" that "Meet all the specifications of the USP/NF, Ph. Eur., JP." NPpharm also states that "[s]ugar spheres are *inert pellets* composed [of] sucrose and maize starch...Suglets are *drug-free cores* which are coated by a suspension or a solution of Active ingredients (with a binder)." See NPpharm Suglets® (emphasis added). As indicated by IPSSrl, "Sugar Spheres (*Neutral pellets*) are *inert microgranules* based on sucrose and corn starch." See IPSSrl, Sugar Spheres (emphasis added). As such, those skilled in the art use "neutral pellets" and/or "neutral cores" synonymously with "inert pellets" and/or "inert microgranules."

Therefore, viewing the specification and interpreting "neutral" in the context of *pharmaceutical preparations*, one skilled in the art would interpret "neutral core" to mean an "inert core" and not necessarily "free of charge" as interpreted by the Examiner. Franz *et al.* do not teach or suggest "neutral cores" as that term is properly interpreted in view of the specification and in the proper context of pharmaceutical preparations (*i.e.*, as "inert cores"). However, as noted above, Applicants have amended the claim to facilitate prosecution of the

application. In view of the foregoing amendments and remarks, Applicants request that the Examiner reconsider and withdraw the rejection under 35 U.S.C. § 102.

Claim Rejections - 35 U.S.C. § 103

In the Office Action, the Examiner also maintained the rejection of Claims 11-20 under 35 U.S.C. § 103 as being unpatentable over Franz *et al.* Applicant respectfully traverse the rejection. As noted above, Franz *et al.* does not disclose coating a “neutral core” as recited in the pending claims. Therefore, Franz *et al.* does not disclose all the limitations of the pending claims.

Further, Franz *et al.* does not suggest the limitations of the present claims. The problem intended to be solved by Franz *et al.* is the preparation of a galenic composition of ergot alkaloids, as a prolonged release formulation with improved bioavailability (col. 1, lines 7-10). Franz *et al.* attempts to solve this problem by applying an *enteric coating* onto an *active core* to prepare a prolonged release formulation (col. 1, lines 28-35). As such, Franz *et al.* emphasizes that the “core” includes the active ingredient, which is a substance other than “sugar, starch, mannitol, sorbitol, xylitol, cellulose, talc, and mixtures thereof” as recited in new claim 23.

In contrast to Franz *et al.*, the claimed process relates to preparing a reproducible, homogenous and stable formulation. The claimed process results in a formulation that includes a high dosage of plant extract, attained by coating a neutral core that “consists of a substance selected from the group consisting of sugar, starch, mannitol, sorbitol, xylitol, cellulose, talc, and mixtures thereof” with a layer containing a plant substance. As such, one skilled in the art, in view of Franz *et al.*, would not be motivated to perform the processes recited in the pending claims.

Furthermore, Franz *et al.* does not teach or suggest applying on a neutral core a layer containing a plant substance wherein “the plant substance is applied in the form of a dry, soft or fluid extract,” and “the layer further comprises polyvinylpyrrolidone as a binder.” The process recited in the instant claims results in a microgranule formulation that is more uniform with respect to the proportion of the plant substance in the microgranules than Franz

et al. because the plant substance is applied as part of an outer layer rather than formulated as part of a core. The process recited in the claims also makes it possible to formulate the microgranules by applying a plant substance from a dry, soft or fluid extract of plant. In contrast, Franz *et al.* does not teach or suggest the use of polyvinylpyrrolidone as a binder for applying a dry, soft or fluid plant extract on a neutral core as recited in the claims. Therefore, Applicants respectfully request that the Examiner reconsider and withdraw the rejection under 35 U.S.C. § 103 over Franz *et al.*

Applicants believe that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested. The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

Respectfully submitted,

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